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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/536,873

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Steven Gamblin

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DLA PIPER US LLP
4365 EXECUTIVE DRIVE
SUITE 1100
SAN DIEGO, CA 92121-2133

EXAMINER

NOAKES, SUZANNE MARIE

ART UNIT

PAPER NUMBER

1656

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/536,873	Applicant(s) GAMBLIN, STEVEN	
	Examiner SUZANNE M. NOAKES	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 and 45-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-43 and 45-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 2, drawn to A crystal comprising a pRb/E2F(409-426) complex, wherein the crystal structure is characterized by the atomic co-ordinates of Annex 1.

Group II, claim(s) 3-13,17-27, 38 and 39, drawn to *in silico* methods of identifying an agent that interacts with a pRb/E2F(409-426) complex.

Group III, claim(s) 14-16, drawn to method of identifying an" agent that modulates a pRb/E2F(409-426) complex by contacting an agent with pRb and E2F(409-426) under conditions in which pRb and E2F(409-426) can form a complex and measuring the binding affinity.

Group IV, claim(s) 28-37, drawn to A method of identifying an agent that modulates a pRb/E2F (409-426) complex, comprising by using fluorescently tagged E2F (409-426) peptide (E2F-fluoropeptide) with pRb to allow pRb/E2F-fluoropeptide complex formation.

Group V, claim(s) 40 and 45, drawn to an *in vitro* method of identifying a compound that interacts with pRb/E2F(409-426) complex by contacting said complex with an agent.

Group VI, claim(s) 41, 42 and 47, drawn to method for the prevention or treatment of proliferative diseases comprising contacting a cell with an agent.

Group VII, claim(s) 43, drawn to a pharmaceutical composition comprising an agent_which modulates the formation of a pRb/E2F(409-426) complex

Group VIII, claim(s) 46, drawn to computer readable media comprising a data storage material encoded with computer readable data, wherein said computer readable data comprises a set of atomic co-ordinates of the pRb/E2F(409-426) crystal structure of Annex 1

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2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. Claim 43 is drawn to a pharmaceutical composition containing an agent which modulates the formation of a pRb/E2F complex.

Xiao et al. (PNAS, 2003, 100(5): 2363-68) teach the following:

“pRb interacts with a number of proteins containing Leu-x- Cys-x-Glu (LxCxE) motifs. These include cellular targets as well as a group of viral oncoproteins such as the papillomavirus E7 protein (11), that binds to pRb preventing complex formation with E2F. The site on pRb that binds to LxCxE-containing peptides is distinct from that which binds E2F because LxCxE based peptides, as opposed to the full-length oncoproteins, do not inhibit E2F binding to pRb (Phelps et al., 1991, J. Virology, 65:6922).” See Xiao et al. (PNAS, 2003, 100(5): 2363-68)

Wu et al. (J. Virology, 1993, 67(4):2402-07) teach a purified protein of human papillomavirus E7 protein. It is noted on p. 2402, 1st column, first paragraph:

“At 100 ng of GST-16 E7, the pRB/E2F complex is completely disrupted (Fig. 1B).”

Phelps et al. (J. Virology, 1991, 65(12):6922-30) teach the purification of a GST-HPV16 E7 protein wherein said protein is purified and stored in a pharmaceutically acceptable composition of 5 mM glutathione, Fusion proteins, 50 mM Tris HCl, pH 8.0. It is noted that this composition anticipates claim 43 for two reasons: First, the manner in which the agent which modulates the formation of a pRb/E2F complex is immaterial and is merely a product by process method wherein the means of forming the product is non-limiting. Second, Xiao et al. and Wu et al. both provide sufficient evidence, both pre-filing and post-filing, that a purified E7 protein, the entire protein, is “an agent” which sufficiently meets the limitations of the instant claim 43.

Thus, claim 43 is anticipated by the teachings of Phelps et al. as evidenced by Xiao et al. and Wu et al.

Therefore, the technical feature linking the inventions of Groups I-VIII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not differentiate the claimed subject matter as a whole over the prior art. Since according to PCT Rule 13.2 the presence of such a common or corresponding special technical feature is an absolute prerequisite for unity to be established, and given that there does not appear to be any other technical feature common to the claimed subject matter as a whole which might be able to fulfill this role, the currently claimed subject matter lacks unity of invention according to PCT Rule 13.1.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Suzanne M. Noakes/
Primary Examiner, Art Unit 1656
25 March 2007